

REMARKS

The undersigned, on behalf of the Applicants, would like to express appreciation to Examiner Hui for the telephonic interview granted on September 8, 2004. The rejection of the claims under 35 USC 112, first paragraph, and in particular, the applicability of the case of *In re Johnson et al* was discussed but no agreement was reached.

Claims 1-21 and 24-26 stand rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement.

The Examiner also noted that the amount of glycerine recited in Claims 22 and 23 appear to be different from the amounts recited in the specification.

THE REJECTION OF CLAIMS 1-21 AND 24-26  
UNDER 35 USC 112, FIRST PARAGRAPH,  
AS FAILING TO COMPLY WITH THE WRITTEN DESCRIPTION REQUIREMENT

In making this rejection, the Examiner cited *In re Johnson*, 194 USPQ 187 (CCPA 1977) for the proposition that,

"If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims."

Applicants traverse this rejection for the following reasons.

The burden of establishing a prima facie case of non-compliance with the written description requirement is on the Examiner. *In re Edwards*, 196 USPQ 465, 469 (CCPA 1978). The Examiner has not met this burden. He simply states that,

"The limitation "said pharmaceutical composition does not contain either an amino acid, citric acid or a pharmaceutically acceptable salt of citric" recited in claims 1 and 24 is not supported by the instant specification."

He has not presented any reason or evidence as to why one skilled in the art would fail to "recognize in the disclosure a description of the invention defined by the claims". 37 USPQ 2d at 1579. *In re Alton*, 37 USPQ 2d at 1583 (quoting *In re Wertheim*, 191 USPQ 90, 97 (CCPA 1976)). Contrary to the Examiner's assertion, there is support for the limitation "said pharmaceutical composition does not contain either an amino acid, citric acid or a pharmaceutically acceptable salt" in the specification.

First, the excluded components are positively disclosed by Applicants in a generic manner on page 7, lines 4-7 of the specification where it is stated,

"If desired the composition of the present invention may further comprise pharmaceutical additives such as coloring agents, flavoring agents, thickening agents, stabilizers, such as sodium deoxycholate, antioxidants such as BHT or vitamin E, and preserving agents such as methyl paraben or propyl paraben".

Citric acid and salts thereof are known in the art to be stabilizers and amino acids are known in the art to be antioxidants (See US Patent No. 5 693 337, of record). These components are positively recited generically in the application as filed and hence the specification meets the written description requirement for the present claims.

Second, support is in Examples 1-5. Each of these Examples describe the invention defined in Claims 1-21 and 24-26 because none of the Examples describe a composition that contains either an amino acid, citric acid or a pharmaceutically acceptable acid of citric acid.

While the present specification does not specifically disclose the stabilizer or antioxidant excluded, this is not required. The subject matter of the claim does not need to be described literally or "in *ipsis verbis*", *In re Lukach*, 169 USPQ 795 (CCPA 1971). All that is required is that the

specification "convey clearly to those skilled in the art the information that the applicant has invented the subject matter later claimed." *In re Wertheim*, 191 USPQ 90, 96 (CCPA 1976); *In re Ruschig*, 154 USPQ 118, 123 (CCPA 1967).

The dilemma created by not allowing an applicant to amend claims as Applicants have in the instant case has been noted by the courts. The *Johnson et al* court noted the following quote of Judge Learned Hand.

"If, when [applicants] yield any part of what they originally believed to be their due, they substitute a new "invention," only two courses will be open to them: they must at the outset either prophetically divine what the art contains, or they must lay down a barrage of claims, starting with the widest and proceeding by the successive incorporation of more and more detail, until all combinations have been exhausted which can by any possibility succeed. The first is an impossible task; the second is a custom already more honored in the breach than in the observance, and its extension would only increase that surfeit of verbiage which has for long been the curse of patent practice, and has done much to discredit it. *It is impossible to imagine any public purpose which it could serve.* [Emphasis added.]"

Third, the court in *In re Johnson* was considering whether a subsequently submitted claim to markush group that was narrower in scope than the specification and original claims was in compliance with the written description requirement. The present claims are directed to a pharmaceutical composition comprising multiple components. The instant claims present a totally different factual situation from that considered in by the *Johnson et al* court. The analysis of whether the written description requirement has been complied with must be done on a case by case basis because it is a factual inquiry. *In re Driscoll*, 195 USPQ, 434, 438 (CCPA 1977).


Claim 24 has been amended by removing the proviso that excludes amino acids, citric acid and salts of citric acid. The proviso was inadvertently added to Claim 4 as the presence of the proviso makes the claim a duplicate of Claim 14. The claim as amended provides specific protection for one of Applicants' more preferred embodiments and it does not introduce new matter (See page 5, lines 14-17). Thus entry of this amendment is respectfully solicited.

INCONSISTENCY OF AMOUNT OF GLYCERINE  
IN THE CLAIMS AND SPECIFICATION

Claim 23 has been amended to recite the amount of glycerine in Example 1. Hence, there is no longer any inconsistency between the specification and claims.

In view of the above amendments and arguments, withdrawal of the rejection and expeditious passage of this case to issue is respectfully submitted.

Respectfully submitted,

  
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